Amendment file

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM

SUBJECT: Amended 7/25/90, Determination of Food/Non-Food Use for a Chemical Hybridizing Agent AC 303,358 (Chembred) on Cotton, to Generate Breeder Seed. ID# 000241-GRI. (MRID # 415716-01, DEB # 7090).

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THRU: Francis B. Suhre, Section Head Francis B. Suhre
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To: Robert Taylor PM-25
Registration Division (H7505C)

The petitioner, American Cyanamid, has submitted additional data on the total radioactive residues (TRR) of AC 303, 358 (Chembred) in or on cottonseed, and has provided an amended label.

Based on this submission, the petitioner requests that DEB re-consider a previous decision that the use of Chembred on cotton reflects a food use.

Chembred is a Chemical Hybridizing Agent (AC 303,358) containing 33.6% potassium 3,4-dichloro-5-isothiazole carboxylate as its active ingredient (28.2% 3,4-dichloro-5-isothiazole carboxylic acid equivalent or 3 lbs ai/gallon).

No tolerances are established for potassium 3,4-dichloro-5-

isothiazole carboxylate.

Background:

AC 303,358 (Chembred) is a chemical hybridizing agent, which can be used on a self-pollinating cotton plant to sterilize selectively the male part of the flower. In the hybridizing process of a cotton plant, two self-pollinating parents are selected for crossing, one is a high yield variety (P1) and the other is disease resistance variety (P2). The two varieties of cottonseed are planted in the same field. Chembred is sprayed on the p1 plant, this will sterilize the male part of a self-pollinating cotton flowers in P1, and the female part then will be fertilized by honey bees, which carry the pollen from P2 plant. The first generation cottonseed produced from this hybridized plant is called F1, which contains both high yield and disease resistance quality. If F1 seed are planted and grown to produce seed, this second generation cottonseed is called F2.

In 1986 Pennwalt Corporation (the original producer of CHA) submitted a tolerance exemption petition (PP#6F3379) for residues of Chembred on cottonseed. We concluded that the proposed use for Chembred on cotton reflects a food use, because the first generation cottonseed (F1) contained residues of AC 303,358 (Chembred). We recommended that the petitioner provide a Section F in which a tolerance is proposed to cover the maximum expected residue level in first generation (F1) cottonseed. We also cited several other deficiencies in this petition (PP#6F3379 M. P. Firestone, 8/8/86).

In 1987 at a meeting with Pennwalt, DEB stated that in order to consider the use of Chembred on cotton a non-food use, a radioactive uptake study must be conducted to determine whether cottonseed from treated plants contained any detectable residues of AC 303,358 (F. Boyd, memo of the meeting dated 3/16/87).

Subsequently, American Cyanamid (subsequent producer of CHA) submitted a total ^{14}C radiolabel residues study, of AC 303,358 on cottonseed and requested an EUP (242-EUP-REN) for the use of Chembred on cotton. The petitioner also requested that we considers this EUP a non-food use. Submitted data indicated that hybrid F1 cottonseed grown from the treated cotton plant with Chembred at 1.8 lb ai/A/season, contained residues of AC 303,358 ranging from 6.5 ppm to 93.9 ppm. No residues of AC 303,358 (Chembred) were detected in second generation or F2 cottonseed. Since this EUP was limited to 100 acres of cotton, we concluded that this can be considered a non-food use. However, for a full registration in the future this use will be considered a food use and a tolerance will be required on F1 cottonseed (241-EUP-REN, L. S. Propst, 6/4/89).

American Cyanamid Company, again requested a determination of food/non-food use status for Chembred on cotton (C. L. Olinger, 1/18/90). The petitioner acknowledged that F1 cottonseed from treated field contains residues, but argued that only 1000 acre of cotton are treated for production of F1 cottonseed. This F1 cottonseed is not for sale, and will be fully controlled by the company. After the F1 cottonseeds are colored, they will be contracted to 33 farmers in the U.S. and each farmer will grow only 1000 acres of cotton. The company will control the growth and production of second generation cottonseed F2 and then F2 cottonseed that do not contain residue of AC 303,358, will be available commercially to farmers (C.L. Olinger, 1/18/90).

We again reminded the registrant that since the first generation of cottonseed (F1), contain residues of AC 303,358, this use is considered a food-use and tolerance must be established for Chembred/metabolites (if any) in or on F1 cottonseed and its processed fractions.

Conclusion

1. Tolerances are not established for Chembred on any crop.

2. Data from radioactive uptake studies of AC 303,358 on cotton showed residues of AC 303,358, in the harvested cottonseed, therefore the proposed use is considered to be a food use.

3. A tolerance for AC 303,358/metabolite in or on F1 cottonseed is required for registration of Chembred for use on cotton.

4. The petitioner's claim that they will control all Chembred treated cottonseeds is not adequate assurance that the treated commodity will not be diverted for human food or animal feed.

Recommendation

CBRS continues to consider the use of Chembred on cotton to reflect a FOOD USE.

Note to PM

The petitioner must resolve the deficiencies cited in our review of PP#6F3379 (C. L. Olinger, 1/18/90) to establish a tolerance for AC 303,358/metabolites in or on F1 cottonseed and its processed fractions.

cc: Chembred (AC 303,358) S.F., R.F., amendment file, Circ., F. Toghrol, FOD/PIB (C. Furlow).
RDI: FBS (2/8/91: EZ (2/19/91):
H7509C:DEB:F.Toghrol:F.T.:RM:802:CM#2:557-7887:2/20/91.